

### REMARKS

Applicant amended independent claim 1 to recite features that the optical fiber has dimensions to modify the input electromagnetic radiation to a modified electromagnetic radiation having one of substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution. These features are similar to the features recited in, for example, dependent claims 13 and 14 and/or independent claim 17. Support for this amendment is also provided throughout the application, including, for example, at paragraphs 19 and 24 on page 2 of the published application (PG Patent Publication No. 2004/0199148). Applicant further amended independent claim 1 to clarify that the modified electromagnetic radiation is what is being applied to the human body. Applicant similarly amended independent claims 26 and 35, and amended independent claim 17 for greater clarity. Applicant also amended claim 36 to correct a typographical error. Applicant cancelled claims 13, 14, 23, 31, 32, 44 and 45.

Additionally, applicant added new claim 48, depending from claim 1, reciting the feature of irrigating an area of the targeted tissue with a solution, and that the outputted modified radiation is applied to the irrigated tissue. Support for this tissue is provided, for example, at paragraph 26 on page 2 and paragraph 40 on page 4 of the published application.

The examiner rejected claims 1-16, 31, 32, 44 and 45 under 35 U.S.C. §112, second paragraph. Specifically, the examiner contended that independent claim 1 does not have an antecedent basis for "the modified laser beam". The amendments to claim 1 described above also address this issue.

The examiner also contended that claims 31, 32, 44 and 45 are substantial duplicates. As noted above, in accordance with applicant's amendments to the independent claims, applicant's claims 31, 32, 44 and 45 have been cancelled. Nevertheless, applicant contends that the subject matter recited in those claims is not necessarily a duplicate. Particularly, a Gaussian distribution is not necessarily the same thing as a Bell-curved shaped intensity distribution.

The examiner further contended that it is unclear what is encompassed by the term "more rounded" recited in claim 15.

In response, to expedite prosecution of the above-identified application, applicant amended claim 15 to clarify that "more rounded" refers to an intensity profile of the modified electromagnetic radiation being greater at positions closer to the center of the fiber than at positions farther from the center of the fiber. Support for this clarification is provided, for

example, at paragraph 24, page 2, of the published application. Applicant similarly amended claims 33 and 46.

The examiner rejected claims 1, 2, 7-12, 15-17, 20-22, 24-27, 30, 33-38, 43 and 47 under U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,304,173 to Kittrell *et al.*

Additionally, the examiner rejected claims 1, 2, 4, 7-11, 15, 17, 19-21, 26, 27, 29, 30, 33, 35, 36, 42 and 46 under U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,738,676 to Hammer *et al.*

Further, the examiner rejected claims 1-3, 6-10, 15, 17, 18, 21, 23-28, 30, 40 and 41 under U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,437,658 to Muller *et al.*

Also, the examiner rejected claims 1, 2, 6-10, 13-17, 21, 23-27, 30-36, 0 and 44-47 under U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,835,647 to Fischer *et al.*

Additionally, the examiner rejected claims 1, 5, 35 and 39 under 35 U.S.C. §103(a) as being unpatentable over Fischer in combination with U.S. Patent No. 6,199,554 to Mann *et al.*

At the outset, applicant respectfully requests that in all subsequent communications the examiner particularly point out, pursuant to the provisions of 37 CFR §1.104 (as they relate to the completeness of an action and rejection of claims) what parts of the prior art references the examiner is relying on so as to enable the applicant to properly address the examiner's rejections. Although the outstanding office action did not provide this level of detail as to what particular portions of the cited references the examiner relied upon, to expedite prosecution of the above-identified application applicant will nevertheless attempt to respond to the examiner's rejections.

Applicant's amended independent claim 1 recites "passing the electromagnetic radiation through a graded index optical fiber, the graded index optical fiber having dimensions to modify the electromagnetic radiation to a modified electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution, the graded index optical fiber outputting the modified electromagnetic radiation; and applying the modified laser beam outputted by the graded index optical fiber to the human body". Thus, it is the graded index optical fiber in applicant's claim 1 that modifies the electromagnetic radiation, and it the electromagnetic radiation so modified that is applied to the human body.

In contrast, none of the cited references relied upon by the examiner discloses or suggests at least the features of "passing the electromagnetic radiation through a graded index

optical fiber, the graded index optical fiber having dimensions to modify the electromagnetic radiation to a modified electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution, the graded index optical fiber outputting the modified electromagnetic radiation,” as required by applicant’s independent claim 1.

Specifically, Kittrell describes optical fibers within a catheter that direct laser radiation for medical applications that include diagnosis and removal of arterial or vascular obstructions (Kittrell, col. 1, lines 16-20). Kittrell explains that in some embodiments the optical fiber may be a graded index optical fiber:

Alternate embodiments of optical fibers 20 include any light conduit. The optical fiber described previously has a core 22 which carries the optical radiation, a cladding 24 of lower index of refraction which confines the radiation, and a jacket or buffer 26 which protects and strengthens the optical fibers 20, FIG. 2. Alternate embodiments include optical fibers 20 without buffer 26, and without buffer 26 or cladding 24. (In the case of core only the surrounding air or gas functions as lower index cladding.) Graded index optical fibers may also be used. The core 22 need not be solid; a fluid filled tube may also be considered an optical fiber 20. A gas or air filled hollow waveguide tube may also be used, and may be made of metal, glass or plastic, with an optional reflective coating inside. Various numbers of optical fibers may be used. In the preferred embodiment, nineteen optical fibers 20 form a symmetric hexagonal close packing array as shown in FIG. 1A. This is likewise true for the seven optical fiber 20 configuration shown in FIG. 3. The sequence for larger numbers of optical fibers is thirty-seven, sixty-one, etc., to form, hexagonal close packing. The optical fibers need not all be the same size or type in a laser catheter. (Kittrell, emphasis added, col. 13, lines 1-23)

However, at no point does Kittrell describe that the graded index optical fiber (or for that matter, any of the optical fibers used in Kittrell catheter) have dimensions to modify the electromagnetic radiation (e.g., laser light) to a modified radiation having a Gaussian, Bell-shaped curve, parabolic, Lorentzian, or other such intensity distributions. Indeed, Kittrell does not at all discuss using or modifying radiation so that the resultant radiation have an intensity distribution having a Gaussian, Bell-curve shape, parabolic and/or Lorentzian distribution. Accordingly, Kittrell fails to disclose or suggest at least the features of “passing the electromagnetic radiation through a graded index optical fiber, the graded index optical fiber having dimensions to modify the electromagnetic radiation to a modified electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution, the graded index

optical fiber outputting the modified electromagnetic radiation,” as required by applicant’s independent claim 1.

Hammer describes a microfocusing laser probe for use in intraocular surgery that uses a gradient index (GRIN) lens (Hammer, col. 3, lines 53-58). Hammer’s laser probe includes a laser source 24, an open transmission line or optical coupler 28 and a gradient index lens 30 (FIG. 3, and col. 5, lines 36-40). Hammer explains that the GRIN lens 30 focuses the laser light produced by the source at a focal point 32 so that laser light 26 will diverge widely past the focal point 32 and decrease to safe levels the energy density applied to the retina during eye surgery (col. 5, lines 53-57).

Hammer further explains that in another embodiment of the probe, a multimode optical fiber is used to deliver laser light to the gradient index lens:

**FIG. 5 shows another intraocular microfocusing laser probe 46 according to the teachings of the present invention. Laser probe 46 uses a multimode optical fiber 48 to deliver laser light 50 from a conventional high power surgical laser 52 to a gradient index lens 54. Optical fiber 48 is tapered to concentrate more energy from laser 52 to gradient index lens 54 to insure sufficient energy density at a focal point 56 to achieve LIB. The taper is exaggerated in this view for clarity. There is an air gap 58 between the end of optical fiber 48 and the back of gradient index lens 54. Air gap 58 couples the output of optical fiber 48 to the entire face of gradient index lens 54 in a more uniform pattern. This allows more power to be transmitted into gradient index lens 54. (Hammer, col. 6, lines 19-32)**

However, at no point does Hammer describe that the optical fiber that may be used with the Hammer’s laser probe is itself a graded index optical fiber. Hammer also does not describe that its laser probe modifies electromagnetic radiation into a modified radiation having one of a Gaussian, Bell-curve shaped, parabolic, Lorentzian or other such types of intensity distribution. Hammer certainly does not describe that the optical fiber (which, as noted, is not a grade-index optical fiber) modifies electromagnetic radiation in such a manner. Hammer, therefore, also fails to disclose or suggest at least the features of “passing the electromagnetic radiation through a graded index optical fiber, the graded index optical fiber having dimensions to modify the electromagnetic radiation to a modified electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution, the graded index optical fiber outputting the modified electromagnetic radiation,” as required by applicant’s independent claim 1.

Muller describes a fiberoptic system for performing laser thermokeratoplasty (Muller, col. 2, lines 66-67). Specifically, Muller’s system includes:

Referring to FIG. 1, a fiber optic multi-fiber delivery system for performing laser thermokeratoplasty includes a laser light generation and coupling system 6, a fiber optic bundle 8, and a fiber optic cap assembly 10. Fiber optic cap assembly 10 includes a thornton ring 40, a rigid dome 12, with eight individual fibers 18 placed in tracks 14 and held in position by a spacer ring 24. Spacer ring 24 sets the proper placement of the individual fiber end housings 20 of optical fibers 18. A prophylactic membrane 36 is placed on cornea 11 and held in place by small protrusions 42 of thornton ring 40 (e.g., protrusions which may project 50 microns and have a corresponding width). The protrusions penetrate prophylactic membrane 36 and the corneal surface to hold thornton ring 40 in place during the laser thermokeratoplasty. (Muller, FIG. 1, and col. 7, lines 7-22)

Muller further describes that an optical lens is coupled to the fiber ends of the fibers 18, but that in some embodiments graded index (GRIN) fibers may be used instead of using lens 23:

Alternatively, instead of using lens 23, the focusing can be achieved using a graded index (GRIN) fiber or by reducing the fiber's diameter at the end to form a convergent fiberoptic waveguide. (Muller, col. 8, lines 15-18)

However, nowhere does Muller describe that the optical fiber modify electromagnetic radiation passing through it to a modified radiation having a Gaussian, a Bell-curved shaped, parabolic, Lorentzian or any other such types of intensity distribution. For that matter, Muller does not even discuss Gaussian, Bell-curved shaped, parabolic and/or Lorentzian electromagnetic intensity distribution. Thus, Muller also fails to disclose or suggest at least the features of "passing the electromagnetic radiation through a graded index optical fiber, the graded index optical fiber having dimensions to modify the electromagnetic radiation to a modified electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution, the graded index optical fiber outputting the modified electromagnetic radiation," as required by applicant's independent claim 1.

Fischer describes a device for generating a laser beam having a homogenized cross section (Abstract). Particularly, Fischer's device includes a solid state laser and a transmission fiber 2 to carry the generated radiation of the laser. The transmission fiber is terminated in a broken surface 4 that is followed by an end piece 5 such as a quartz rod:

The radiation exiting therefrom enters a transmission fiber 2. This is a fiber having a length of at least 0.2 m and an external diameter of between 50 and 1000  $\mu\text{m}$ . The transmission fiber 2 consists, for example, of  $\text{ZrF}_4$  or of another material which is transparent to the wavelength emitted by the solid-state laser 1. This wavelength is between 2 and 3  $\mu\text{m}$  in the stated substances.

At the free end 3, the transmission fiber 2 terminate in a broken surface 4 and is followed at a spacing of between 0 and 20 mm by an end piece 5, for

**example, a quartz rod having a length of between 5 and 50 mm. (Fischer, col. 3, lines 45-55)**

Thus, radiation exiting the transmission fiber's end is directed to an optical component (namely, end piece 5) and not to the target tissue. Fischer further describes that fiber with a stepped profile or with graded-index profile may be used, and further explains that:

**The laser radiation generated by this device is emitted divergently and exhibits a rotationally symmetrical radiation distribution which is mode-homogenized. For example, the intensity distribution over the cross section, which is indicated by way of an example in the drawing, can be a Gaussian distribution, a super Gaussian, a parabolic or also a ring-shaped distribution. This depends, inter alia on the length of the transmission fiber, on the entrance angle into the transmission fiber and also on the flexure of the transmission fiber. (Fischer, col. 3, line 62 to col. 4, line 4)**

Thus, a Gaussian distribution (or other forms of distributions) of the output radiation are generated by the interplay of the fiber 2 and the end piece 5 of Fischer's device. Indeed, as shown in FIG. 1, a resultant Gaussian intensity distribution is formed at the end face 8 of the end piece 5. In other words, unlike applicant's independent claim 1, it is the combination of the transmission fiber 2 and the end piece 5 that produces the desired intensity distribution. Fischer's transmission fiber does not by itself modify the radiation passing through it to a particular intensity distribution such as a Gaussian distribution. Accordingly, Fischer also fails to disclose or suggest at least the features of "passing the electromagnetic radiation through a graded index optical fiber, the graded index optical fiber having dimensions to modify the electromagnetic radiation to a modified electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution, and the graded index optical fiber outputting the modified electromagnetic radiation," as required by applicant's independent claim 1.

Mann describes a method of enhancing injury-induced revascularization of a tissue as treatment of a disease (Abstract). Mann describes using heat-directing means, such as a laser source, to create a channel in the target tissue (Mann, col. 8, lines 12-23). Mann, however, does not describe use of optical fibers to direct radiation, and Mann certainly does not describe optical fibers to modify electromagnetic radiation having a Gaussian, Bell-shaped curve, parabolic, Lorentzian and/or other types of intensity distributions. Indeed, Mann does not at all discuss modifying electromagnetic radiation (such as laser radiation) so that the modified radiation have an intensity distribution such as a Gaussian, Bell-curved shaped, parabolic, Lorentzian, etc.,

intensity distribution. Accordingly, Mann also fails to disclose or suggest at least the features of “passing the electromagnetic radiation through a graded index optical fiber, the graded index optical fiber having dimensions to modify the electromagnetic radiation to a modified electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution, the graded index optical fiber outputting the modified electromagnetic radiation,” as required by applicant’s independent claim 1.

Because none of the cited references discloses or suggests, alone or in combination, at least the features of “passing the electromagnetic radiation through a graded index optical fiber, the graded index optical fiber having dimensions to modify the electromagnetic radiation to a modified electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution, the graded index optical fiber outputting the modified electromagnetic radiation,” applicant’s independent claim 1, and the claims depending from it, are therefore patentable over the cited prior art references.

Applicant’s independent claims 17, 26 and 35 recite “passing the laser beam through an optical fiber, the optical fiber configured to modify the laser beam to a modified laser beam having an intensity distribution corresponding substantially to a Gaussian intensity distribution,” or similar language. For reasons similar to those provided with respect to independent claim 1, at least these features are not disclosed by the cited prior art references. Applicant’s independent claims 17, 26 and 35, and the respective claims depending from them, are therefore patentable over the cited art.

CONCLUSION

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

On the basis of the foregoing amendments, applicant respectfully submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the examiner is encouraged to contact the undersigned at the telephone number provided below.

The Commissioner is hereby authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 35678-604C01US.

Respectfully submitted,

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